II. RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 40-44 and 53 were pending prior to the Office Action dated October 20, 2004. Claims 40 and 53 have been amended and claims 54-59 have been added. Support for the amendments and new claims may be found throughout the specification, for example, at page 4, lines 22-30. No new matter has been added. Thus, claims 40-44 and 53-59 are currently pending.

B. Specification Amended

The specification has been amended to recite the priority claim, as is evidenced by the submitted inventor declarations.

C. Claims Are Adequately Described

The Action rejects claims 40-44 and 53 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants do not agree that the claims fail to adequately describe the invention, but in the interests of expediting prosecution, Applicants' claims recite:

The Federal Circuit has stated that the test for the written description requirement is "whether the application relied upon 'reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter.'" *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998). See also *Markman v. Westview Instruments, Inc.* 52 F.3d 967, 34 USPQ 2d 1321 (Fed. Cir. 1995) (en banc) ("Claims must be read in view of the specification, of which they are a part."). In rejecting a claim under the written description requirement of 35 U.S.C. §112, first paragraph, the Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant's

disclosure a description of the invention defined in the claims. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

1. Claims Recite Structural or Chemical Properties

The Guidelines for the Examination of Patent Applications Under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement. Action state that the "written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, *i.e.,* structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." Page 1106 (emphasis added). While a structure/function relationship may be relied upon to satisfy the written description requirement, it is not absolutely required.

In this case, the claims recite specific structural and chemical properties of the claimed SM22α promoter region by identifying SEQ ID NO:1. SEQ ID NO:1 is adequately described in the specification.

In fact, from a pure mathematical point of view, the number of species disclosed by the specification with respect to each claim is numerous. For example, with respect to claim 40, which recites "an SM22α promoter region comprising 50 contiguous bases of SEQ ID NO:1 in the region upstream of the transcriptional start site," a person of ordinary skill in the art would understand that the specification disclosed at least *thousands* of different species based on the disclosure of SEQ ID NO:1. This is true for each of the rejected claims. Even an undergraduate student who has taken an elementary molecular biology course could identify many different

species that satisfied the claims based simply on the disclosed sequence. Applicants note that the specification indicates that the region upstream of the transcriptional start site is position 1341 of SEQ ID NO:1. *See* page 4 of specification.

Based on the number of disclosed species, the specification necessarily satisfies the written description requirement because it reasonably conveys to one of skill in the art that they had possession of the claimed subject matter. *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790.

A patentee does not need to describe every embodiment on which the claim reads. According to the Federal Circuit, "[i]t is well-established that a patent applicant is entitled to claim his invention generically, when he describes it sufficiently to meet the requirements of section 112." *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991); *see also Utter v. Hiraga*, 856 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) ("A specification may, within the meaning of 35 U.S.C. §112, paragraph 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.").

The written description requirement has been extensively addressed by the Federal Circuit. In particular, the Federal Circuit has stated that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ 2d 1227, 1232 (Fed. Cir. 2000). The Federal Circuit has also noted that "[if] a person or ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly

described in the specification, then the adequate written description requirement is met." *In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996). Consequently, based on what is recited in the claims—portions of SEQ ID NO:1, a person of skill in the art would understand that the inventor was in possession of the claimed subject matter based on the structural or chemical description of SEQ ID NO:1.

In accordance with the Federal Circuit's requirements pertaining to written description, one of ordinary skill in the art would have understood that Applicants were in possession of SM22α promoter regions having [50, 100, or 500] contiguous bases from SEQ ID NO:1 or the entire region upstream of the transcriptional start site in SEQ ID NO:1.

2. Established Patent Law Requires Only That the Specification Set Forth the Invention

The Federal Circuit in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991), cited a Supreme Court opinion that the second requirement of paragraph 112 was:

> "to put the public in possession of what the part claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is, therefore, for the purpose of warning an innocent purchaser, or other person using . . . [the invention], of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification."

Evans v. Eaton, 20 U.S. (7 Wheat.) 356 (1822). Applicants' specification makes clear what the invention is so as to put the public on notice. There can be no dispute that they have described what they now claim. The specification and originally filed claims provide literal support for the presently rejected claims and, as discussed above, Applicants set forth structural and chemical

limitations in the claims. As argued in the previous Response, this distinguishes the present situation from the case of *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). In *Eli Lilly*, the patentee claimed a human insulin cDNA but no sequence information was provided. Instead, only a way to obtain the sequence was disclosed. In contrast, Applicants have provided the requisite chemical structures for the claimed methods involving an SM22α promoter.

Clearly, the rejected claims recite common structural limitations—an SM22α promoter region having contiguous bases from SEQ ID NO:1. The specification fully discloses SEQ ID NO:1.

Even if functional information were required, the specification provides relevant information regarding the SM22α structure and its activity. In Example 1 the isolation and initial characterization of the mouse SM22α promoter are described. In Examples 13 and 14, data are provided regarding *cis*-acting regulatory sequences and their trans-acting factors that are involved in expression from the SM22α promoter region.

The specification fully supports the claimed methods. It is respectfully requested that this rejection be withdrawn.

D. Double Patenting

Applicants are submitting terminal disclaimers over U.S. Patents 6,114,311; 6,284,743; 6,291,211; and, 6,331,527 (Tab 1). As the Office (and public) should be aware, the filing of a terminal disclaimer does not create any estoppel or presumption regarding the merits of the rejection. *Quad Environmental Tech. Corp. v. Union Sanitary Dist.*, 946 F.2d 870 (Fed. Cir. 1991). The terminal disclaimers address this rejection, and Applicants respectfully request its withdrawal.

CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

Should the Examiner desire to sustain any of the rejections discussed in relation to this Response, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3081 is respectfully requested.

Respectfully submitted,

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Date: April 20, 2005